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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,715	04/19/2000	MAMORU OHASHI	2000-0486A	9675

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/529,715	OHASHI ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7,8,13,15,16,89,90 and 92-117* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5, 7-8, 13, 15-16, 89-90, and 92-117* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☑ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Receipt of the Request for Continued Examination and Rule 132 Declarations C-E of 6/1/05 and the Information Disclosure Statement of 7/21/05 is acknowledged. Claims **1, 3-5, 7-8, 13, 15-16, 89-90, and 92-117** are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 7-8, 13, 15-16, 89-90, and 92-117 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Firstly, applicant has amended the independent claims to recite "excepting a nanoparticle suspension"; however a careful review of the instant disclosure does not provide support for such a limitation.

Secondly, applicant has amended claim 4, 8, 16, 92, 94, 98, 100, 104, 106, 110, 113, 115 recite the particle size "**about 1.2**" microns, which does not find support in the instant specification. Moreover, the amended particle size range of "**above 1**" micron to less than about 10 micron in the independent claims do not have support in the instant specification. It should be noted that the range of above 1 micron to less than 20 microns as previously claimed should have been rejected under new matter upon reconsideration since the range also does not have support

in the instant specification. A careful review of the specification provides support for about 1.5 microns on page 10, the range of 0.5 to 3 microns finds support on page 4, less than 10 microns finds support on page 4, and less than 5 microns finds support on page 4. However, the range of "above 1 micron" to 10 microns does not find support; although the specification discloses less than 10 microns, it does not disclose the lower limit of the range, i.e. above 1 microns. It is noted applicant is attempting to claim ranges stating there is inherent of implicit support on page 4. The examiner points out that this statement is not sufficient to demonstrate that applicant had possession of the claimed range at the time of filing. It should be noted that although the claimed range of dependent claims 95, 96, 101, 102, 107, 108, 114, and 116 have support in the specification, the claims have been rejected under new matter since they dependent on claims independent claims 1, 5, and 89.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3, 7, 15, 92-93, 98-99, 104-105, and 110-112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Dependent claim 3 is directed to a mean particle size of "less than 5 microns" which includes all sizes below 5 microns without a lower limit. However, this is vague and indefinite since the independent claim is directed to a particle size of above 1 micron to less than about 10 microns, wherein the independent claim has a maximum limit. This instance also occurs in claims 7, 15, and 112.

Dependent claim 92 is directed to a mean particle size of "above about 1.2 microns" which includes all sizes above 1.2 microns without a maximum limit. However, this is vague and indefinite since the independent claim is directed to a particle size of above 1 micron to less than about 10 microns, wherein the independent claim has a maximum limit. This instance also occurs in claims 93, 98-99, 104-105, and 110-111.

Further clarification and restructuring the claim is requested.

Although claim 5 is not rejected, the examiner suggests defining AS-3201 in independent claim 5 (as previously done in independent claim 1 and 89).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5, 7, 13, 15, 97, 103, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Negoro et al (5,258,382) in view of Muller et al (5,858,410).

Negoro et al teach the instantly claimed aldose reductase inhibitor compound in a pharmaceutical composition for the treatment of diabetes (see abstract). The reference discloses the aldose reductase inhibitor in fine granules (1%) with a diluent (73%), a binder (3%), a lubricant (1%), and disintegrator (22%) (See example 29).

Negoro et al does not specify the particle size of the active or the dissolution rate.

Muller et al teach pharmaceutical compositions containing an active that is insoluble or sparingly soluble in water, an aqueous medium, or solvent. Muller discloses that the dissolution

rate increases as the particles surface area increases in accordance with the Noyes-Whitney law. As a result of the increased dissolution rate, the bioavailability increases (col. 1, lines 44-50). Muller discloses a marked increase in saturation solubility and in turn dissolution with the reduction of particle diameter and increased surface area from microns to nanometers (col.5, lines 58-60 and col. 7, lines 7-10). The reference teaches a particle in the range of 10 to 1,000 nm, corresponding 0.01 to 1 micron, and 65% dissolution rate within ten minutes (col. 2, lines 40, col. 14, lines 49-55 and figures).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Negoro and Muller and reduce the particle size of the active instant range. One would have been motivated to do so since Muller et al disclose that an increased surface area through reduction of particle size allows for a faster rate of dissolution. Although Muller teaches the range of 0.01 to 1 micron and instant range is "in a range above 1 micron", it is deemed obvious to a skilled artisan to manipulate and tweak the prior art's particle range to obtain optimum results thorough routine experimentation. Further, one would expect similar results since Muller teaches a sparingly soluble or insoluble drug and the instant active agent is also sparingly soluble. Therefore, a skilled artisan would have been motivated to decrease the particle size to that of Muller's particle range to provide for a faster dissolving composition with increased bioavailability in the body.

Response to Arguments and Rule 132 Declaration C and D

Applicant argues that Muller is directed to nanoparticle suspension and not to a solid dosage form having microparticles. It should be noted that applicant's arguments pertain to the article size of the drug, which has been rejected under 112, first paragraph as new matter.

Applicant's arguments have been fully considered but they are not persuasive. Again as pointed out in the Final Office Action of 12/1/04, the argument that Muller is concerned with nanometer ranges instead of applicant's micrometer ranges is insufficient since the nomenclature "micro" versus "nano" is not enough to distinguish over the art since Muller teaches the upper limit of 1000nm, which when converted into micrometers is 1 micrometer. Therefore, depending on an artisan preference to call the particle size 1000 nanometers or 1 micrometer, the particle size remains the same. Thus, the obviousness rejection is based on the fact that Muller et al teach a range of 0.01 to 1 micron or 10nm to 1000nm and applicant merely recites "above 1 micron" which falls under an obvious scope and parameter of the prior art. For instance, 1.001 is above Muller's 1 micron, however it is still an obvious parameter to a skilled artisan thorough routine optimization.

With regard to the argument Muller only teaches nanosuspensions and not solid dosage forms, it is pointed out that the broad terminology "solid dosage forms" encompasses Muller's nanosuspensions since suspensions are solid particles suspended in an immiscible liquid. Thus, Muller does in fact teach solid particles.

Applicant argues that the examiner has improperly applied that Noyes-Whitney law and that it does not pertain to every compound as confirmed by the Board. Applicant argues that AS-3201 is a hydrophobic drug; thus this is an extraordinary circumstance. Applicant argues that the instant Declaration C demonstrates that AS-3201 is not conformable to Noyes-Whitney law.

The examiner points out that Muller teaches micronizing a variety of drugs including hydrophobic drugs; thus Muller teaches the micronization of drugs with "extraordinary circumstances". See column 9-10. Therefore, Muller demonstrates that the Noyes-Whitney law

does not only apply a certain type of pharmaceutical composition, rather it is a theory that can be applied to a variety of pharmaceutical compositions including water-insoluble and water-soluble drugs. With regard to the Rule 132 declaration of 9/9/04, this declaration merely demonstrates that AS-3201 is a hydrophobic drug but the declaration does not demonstrate that the Noyes-Whitney law does not apply as argued by applicant.

With regard to Declaration C, applicant is comparing a particle size of .63 microns and to a particle size of 1.36 microns; however applicant does not have support for a lower limit other than about 1.5 microns; thus this argument is moot. Further, the examiner points out that the rejection is based on the fact that "above 1 micron" and Muller's 1 micron are within an obvious range. However, the declaration does not demonstrate the unexpectedness of a particle size of 1 micron compared to a size of "above 1 micron", i.e. 1.001 micron, as claimed. Lastly, it is noted that applicant compares a tablet comprising particles with a size of 0.63 microns and a tablet comprising particles with a size of 1.36 microns and concludes that the dissolution rate is the same. However, firstly the claims are directed to solid dosage forms and not solely to tablets. Therefore, firstly the claims are not commensurate in scope with the claims. Secondly, to provide the unexpectedness of the broad genus, applicant should compare the individual particle and their dissolution rates.

With regard to Declaration D, it is unclear what this declaration is intended to demonstrate. Applicant compares a tablet comprising particles with the size 1.36, 1.62, and 1.18 microns respectively and concludes that the tablet comprising particles with a size of 1.18 microns have the best dissolution. The examiner notes that this is in concurrence with the Noyes-

Whitney law wherein as the surface area of the particle increases via particle reduction, dissolution increases.

Accordingly, the rejection is maintained.

Claims 1, 3-5, 7-8, 13, 15-16, and 92-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Negoro et al (5,258,382) in view of Arbuthnot et al (6,458,811).

Negoro et al teach the instantly claimed aldose reductase inhibitor compound in a pharmaceutical composition for the treatment of diabetes (see abstract). The reference discloses the aldose reductase inhibitor in fine granules (1%) with a diluent (73%), a binder (3%), a lubricant (1%), and disintegrator (22%) (See example 29).

Negoro et al does not specify the particle size of the active or the dissolution rate.

Arbuthnot et al teach a benzothiophene compound in particulate form with a mean particle size between 5 and about 20 microns. See column 2, lines 66-67. Arbuthnot states that it has been found that tweaking the particle size within a specified range, the pharmaceutical composition may be prepared to exhibit a consistent vitro dissolution profile and in vivo bioavailability. Further, the reference states that by controlling the particle size to a narrow range, it has also results in improved manufacturing capabilities. See column 3, lines 15-32. It is noted by Arbuthnot that a compromise between the particles size and manufacturing exists, however the method for determining the particle size is known in the art. See column 22, lines 16-56. Arbuthnot states that compounds with poor solubility can have their bioavailability enhanced by increasing the surface area of the particles. Further, Arbuthnot states that the aqueous solubility of a drug potentially impacts the dissolution rate of the solid dosage form since the dosage form and the active are exposed to the gastrointestinal tract. Thus, the two

related physical properties of drugs, the surface area and particle size, can alter the dissolution rate of the dosage form. The impact of surface area, which is a function of particle size is illustrated by the Noyes-Whitney equation. See column 24, lines 25-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Negoro and Arbuthnot et al and reduce the particle size of the active to the instant range. One would be motivated to do so since Arbuthnot discloses that an increased surface area through reduction of particle size allows for a faster rate of dissolution of the active and the solid dosage form. Further, Arbuthnot et al teach that increasing the surface area thorough the reduction of particle size, as taught by the Noyes-Whitney law, increases the bioavailability of sparingly soluble drugs. Thus, one would have been motivated to encompass the teachings of Arbuthnot since the instant active agent is also sparingly soluble.

Therefore, a skilled artisan would be motivated to decrease the particle size to that of Muller's particle range to provide for a faster dissolving composition with increased bioavailability in the body.

Note that the dependent claims that recite a range of less than 5 microns and 1 micron to 5 microns, are deemed to be obvious parameters in the art done thorough routine experimentation to obtain the best results. One would be motivated to do so since Arbuthnot teaches that the method of determining the best mean particle size for a drug is readily known to one of ordinarily skill in the art. Further, Arbuthnot provides the guidance in experimenting to find the optimal particle size.

Response to Arguments and Rule 132 Declaration C and D

Applicant argues that although size reduction is in general considered to be prima facie obvious; each case must be individually evaluated. Applicant argues that the instant case has extraordinary circumstances and thus size reduction is not obvious. Applicant argues that Arbuthnot's raloxifene and instant AS-3201 are not the same compounds. Lastly, applicant argues that the Noyes-Whitney law cannot apply to every compound.

Applicant's arguments have been fully considered but they are not persuasive.

Firstly, the examiner notes that the two drugs are not the same, the examiner utilizes the secondary reference to teach the Noyes-Whitney law with regard to solid dosage forms.

With regard to the assertion that the Noyes-Whitney law does not apply to every compound, the examiner does not assert that this law applies to every compound known. The examiner merely notes that this is a general theory that is a starting point to experiment. Clearly Arbuthnot provides this motivation by teachings that increasing the surface area thorough the reduction of particle size, as taught by the Noyes-Whitney law, increases the bioavailability of sparingly soluble drugs.

With regard to Declaration C, applicant is comparing a particle size of .63 microns and to a particle size of 1.36 microns; however applicant does not have support for a lower limit other than about 1.5 microns and thus this argument is moot. Further, it is noted that applicant compares a tablet comprising particles with a size of 0.63 microns and a tablet comprising particles with a size of 1.36 microns and concludes that the dissolution rate is the same. However, firstly the claims are directed to solid dosage forms and not solely to tablets. Therefore, firstly the claims are not commensurate in scope with the claims. Secondly, to provide

the unexpectedness of the broad genus, i.e. solid dosage forms, applicant should compare the individual particle and their dissolution rates.

With regard to Declaration D, it is unclear what this declaration is intended to demonstrate. Applicant compares a tablet comprising particles with the size 1.36, 1.62, and 1.18 microns respectively and concludes that the tablet comprising particles with a size of 1.18 microns have the best dissolution. The examiner notes that this is in concurrence with the Noyes-Whitney law wherein as the surface area of the particle increases via particle reduction, dissolution increases.

Accordingly, the rejection is maintained.

Claims 89-90, 110-113, and 115-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Negoro et al (5,258,382) in view of Muller et al (5,858,410) or Arbuthnot et al (6,458,811) in further view of Schneider et al (5,356,636).

As set forth above, Negoro et al teach the instant active in a solid dosage form. Muller et al and Arbuthnot et al teach the reduction of particle size to increase dissolution. Muller et al teach the use of stabilizers to cover the surface of the particles to prevent aggregation (col. 7).

The references do not teach the instant acids in the composition.

Schneider et al teach the use of stabilizers or antioxidants when the active agent is sensitive to oxidation. Stabilizers such as the instant acids are taught on column 4, line 68.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instant acids in the composition of Negoro et al. One would be motivated to do so since Schneider et al teach these acids as stabilizers for the active agents. Thus, it is considered obvious to a skilled artisan to pursue the stability of an active against oxidation.

Response to Rule 132 Declaration E

Declaration E under 37 CFR 1.132 filed 6/1/05 is insufficient to overcome the rejection based upon Negoro et al (5,258,382) in view of Muller et al (5,858,410) or Arbuthnot et al (6,458,811) in further view of Schneider et al (5,356,636) since the claims are not commensurate in scope. Applicant utilizes a specific particle size of 1.5 microns to show that a tablet comprising an acid compared to tablet without acid is unstable. It should be noted that these claims have been rejected under new matter rejection and double patenting rejection. The examiner suggests either placing the claim limitation of 114 or 116 into the independent claim 89 to overcome the new matter rejection and place the claims commensurate in scope with the declaration. Further, the examiner suggests filing a Terminal Disclaimer to overcome the double patenting rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 7-8, 13, 15-16, 89-90, and 92-117 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,297,244 in view of Arbuthnot et al (6,458,811).

US patent claims a pharmaceutical composition containing AS-3201 and "at least one acidic substance having an acidity more potent than that of said active ingredient." Claims 4-6 recite an acidic Markush group of citric acid, tartaric acid, maleic acid, and phosphoric acid.

Instant application claims a solid dosage form containing "AS-3201" (Note the chemical name in claim 1) with a mean particle size in a range of above 1 micron to less than about 20 microns. Claim 61 claims a stabilizer of "at least one acidic substance having an acidity more potent than that of AS-3201". Claim 62 claims an acidic Markush group of citric acid, tartaric acid, maleic acid, and phosphoric acid.

US patent does not claim the instant particle size.

Arbuthnot et al teach a benzothiophene compound in particulate form with a mean particle size between 5 and about 20 microns. See column 2, lines 66-67. Arbuthnot states that it has been found that tweaking the particle size within a specified range, the pharmaceutical composition may be prepared to exhibit a consistent vitro dissolution profile and in vivo bioavailability. Further, the reference states that by controlling the particle size to a narrow range, it has also results in improved manufacturing capabilities. See column 3, lines 15-32. It is noted by Arbuthnot that a compromise between the particles size and manufacturing exists, however the method for determining the particle size is known in the art. See column 22, lines 16-56. Arbuthnot states that compounds with poor solubility can have their bioavailability enhanced by increasing the surface area of the particles. Further, Arbuthnot states that the

aqueous solubility of a drug potentially impacts the dissolution rate of the solid dosage form since the dosage form and the active are exposed to the gastrointestinal tract. Thus, the two related physical properties of drugs, the surface area and particle size, can alter the dissolution rate of the dosage form. The impact of surface area, which is a function of particle size is illustrated by the Noyes-Whitney equation. See column 24, lines 25-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of US patent and Arbuthnot et al and utilize the instant application particle range. One would be motivated to do so since Arbuthnot discloses that an increased surface area through reduction of particle size allows for a faster rate of dissolution of the active. Further, Arbuthnot et al teach that increasing the surface area thorough the reduction of particle size, as taught by the Noyes-Whitney law, increases the bioavailability of sparingly soluble drugs. Thus, one would be motivated to encompass the teachings of Arbuthnot since the instant active agent is also sparingly soluble. Therefore, a skilled artisan would be motivated to decrease the particle size to that of Muller's particle range to provide for a faster dissolving composition with increased bioavailability in the body.

Conclusion

All the claims are rejected at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

GARY KUNZ
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